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THINGS WE DO FOR NO REASON™

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Things We Do for No Reason™: Prescribing gabapentinoids for pain

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Abstract

Gabapentin and pregabalin are among the most frequently prescribed medications in the United States, with gabapentin in the top 10 and pregabalin in the top 100. Despite FDA approval for only select neuropathic conditions, most use is for off-label pain indications. Randomized trials show minimal or clinically insignificant benefit for most off-label pain syndromes. In contrast, gabapentinoids are associated with sedation, falls, delirium, respiratory depression, misuse, and hospitalization, especially with opioids or renal impairment. Given limited efficacy and harms, they should not routinely substitute for opioids. Clinicians should reassess indications, deprescribe when appropriate, and prioritize nonpharmacologic strategies.

A CLINICAL SCENARIO

A 61-year-old man with chronic back pain, asthma, and chronic kidney disease is admitted with acute on chronic lower back pain radiating to the left leg. His pain is uncontrolled despite ibuprofen and hydrocodone. Magnetic resonance imaging shows disc herniation and S1 nerve root compression. The hospitalist prescribes gabapentin 300 mg every 8 h.

BACKGROUND

The use of gabapentinoids has risen over time, with 70 million gabapentin prescriptions and 6.5 million pregabalin prescriptions in the United States in 2021.[1] The same year, sales reached $1.5 billion for gabapentin and $5.5 billion for pregabalin. Though the antinociceptive mechanism of action of these GABA—analogues is not fully understood, both drugs bind to the α2δ subunit of calcium channels, inhibiting the tonic phase of nociception. About 90% of pregabalin is absorbed, while gabapentin absorption is saturable and, therefore, unpredictable at higher doses.

According to the full prescribing information on the package labels, gabapentin is indicated for postherpetic neuralgia, while pregabalin is indicated for painful diabetic peripheral neuropathy (DPN), fibromyalgia, and spinal cord injury pain. Both are also indicated for adjunctive treatment of partial-onset seizures. Approximately 83% of gabapentinoid prescriptions are for off-label pain management.[2] Hospitalists often see patients with acute on chronic pain and initiate gabapentinoids for multimodal analgesia, and postoperative and neuropathic pain; about half of these patients are discharged on gabapentin.[3]

WHY YOU MIGHT THINK GABAPENTINOIDS ARE HELPFUL FOR PAIN

The CDC's 2024 update reports that 24% of adults experience chronic pain.[4] Among inpatients, one in five have chronic pain, with nearly 70% reporting acute-on-chronic episodes and frequent disruption of sleep and mood.[5] Drug treatment of pain is challenging: acetaminophen is often ineffective for severe pain, nonsteroidal

anti-inflammatory drugs have short and long-term risks, and partial opioids vary in effectiveness due to interpatient variation in pharmacogenetics.[6] Opioids are effective for severe acute pain but less effective for chronic pain; they pose a risk of serious harm, including addiction, respiratory depression, and death. Efforts to limit opioid prescriptions have led to widespread use of gabapentinoids for pain.

The 2016 CDC guidelines mention the use of gabapentin or pregabalin as non-opioid alternatives for chronic neuropathic pain, contributing to the perception that these medications offer better efficacy and safety than opioids.[7]

WHY YOU SHOULD AVOID TREATING PAIN WITH GABAPENTINOIDS

Lack of efficacy

Well-conducted randomized controlled trials (RCTs) for off-label indications for gabapentin and pregabalin showed minimal or no benefit over placebo (Tables 1 and 2). Most neuropathic pain trials of gabapentin and pregabalin have been of short duration-many as brief as 3 weeks, few extending beyond 3 months, and none lasting more than 6 months.[8,9] In 2002, the FDA rejected labeling of gabapentin for neuropathic pain and DPN due to insufficient evidence. Despite this, Pfizer chose to market gabapentin for off-label use in patients with chronic pain.

In 2004, Pfizer settled a $430 million lawsuit with a whistleblower and also settled a separate $325 million lawsuit with third-party payors.[10] In 2009, Pfizer settled a dispute with the US Department of Justice for $2.3 billion for off-label promotion of pregabalin and three other drugs.[11] Comparison of internal Pfizer documents with peer-reviewed articles found systematic distortion giving "a more favorable presentation in the medical literature of gabapentin's efficacy for unapproved indications."[12] Separately, an analysis of court documents found that Pfizer used its influence with key opinion leaders regarding gabapentin so as to suppress or delay reporting of unfavorable clinical trials, to influence the conduct of clinical trials and to distort reporting of published research articles about gabapentin.[13]

Among five RCTs of gabapentin in painful DPN, the two largest and longest trials showed no benefit (Table 1); three small placebo-controlled trials reported nominal pain score improvements (1.1, 1.2, and 1.9 points, respectively) on a 0-to-10 pain scale.[9] Differences of 1 point or less are considered clinically insignificant.[14] A Cochrane review of gabapentin for painful DPN showed more subjects (38%) had substantial benefit (at least 50% pain relief) with gabapentin at 1200 mg daily or greater compared to placebo (23%) (relative risk [RR] 1.7, 95% confidence interval [CI]: 1.4–2.0); number need to treat (NNT) 6.6 (5.0–10).[15] However, adverse events were common (RR: 1.3, 95% CI: 1.2–1.4) with a number needed to harm (NNH) of 7.5 (6.1–9.6). In addition, study dropouts were excluded in primary analyses, potentially leading to falsely elevated efficacy estimates.

Pregabalin was approved by the FDA for DPN based on five RCTs.[8] Three of those trials were supportive, one was partly supportive, and one (unpublished) was negative.

Gabapentinoid use in nondiabetic neuropathies is limited. Most recent clinical studies have focused on short-term treatment for postoperative pain.[16] Trials have shown either negative results or minimal improvements for off-label conditions—typically less than 1 point on a 0-to-10 pain scale (Tables 1 and 2).[9] Evidence does not support gabapentinoid use for low back pain or radiculopathy, and the largest placebo-controlled trial of pregabalin for acute and chronic sciatica found it to be ineffective with increased adverse drug events.[9,17] A Cochrane review further confirmed that, aside from postherpetic neuralgia (FDA-approved for gabapentin and pregabalin) and DPN (FDA-approved for pregabalin), evidence for gabapentinoids in other neuropathic pain conditions remains limited.[15]

Adverse effects

Meta-analyses of gabapentinoids show dose-dependent adverse effects (NNH 3–11), with up to one-third experiencing dizziness or somnolence. One large trial reported dizziness in 40% of pregabalin users versus 13% on placebo.[9] Gabapentinoids may also significantly increase the risk for falls when combined with opioids.[18]

Gabapentinoids do have a modest effect on reducing postoperative pain but increase the risk of delirium, pneumonia, and new antipsychotic use.[19] Most of the gabapentinoid clinical trials used for FDA approval excluded central nervous system (CNS) depressants (e.g., opioids, benzodiazepines, muscle relaxants). In 2019, the FDA warned that gabapentin and pregabalin can cause fatal respiratory depression, particularly when combined with other CNS depressants or in the setting of respiratory impairment. The alert was based on 49 cases of respiratory depression, including 12 deaths.[20] The FDA published warnings that gabapentin can rarely cause respiratory depression, particularly when combined with other drugs that cause respiratory depression.[8] The risk of opioid overdose increases seven–fold with concomitant gabapentinoid use (hazard ratio [HR]: 6.10, 95% CI: 4.11–9.06).[21] Among 13,504 COPD patients, gabapentinoid initiation was linked to a significantly higher risk of severe COPD exacerbations (HR: 1.39, 95% CI: 1.29–1.50).[22]

Observational cohort studies have linked gabapentinoids to a higher risk of fractures, particularly in frail individuals and those with chronic kidney disease.[23] Additionally, gabapentin use in patients with fibromyalgia has been associated with increased cardiovascular risks, including myocardial infarction, heart failure, and thromboembolic events, while pregabalin showed elevated risks for deep vein thrombosis and pulmonary embolism.[24] Gabapentin-induced peripheral edema also affects 2%–8% of users.[25]

A study of US veterans found that even low-dose gabapentin was associated with significantly increased hospitalization risk.[26] Another study linked gabapentin initiation to a higher risk of hospitalization for altered mental status.[27]

TABLE 1 Randomized clinical trials of gabapentin versus placebo for off-label treatment of pain.

Study	Condition	No. of participants	Duration (weeks)	Significant difference in pain compared to placebo	Gabapentin dose
Rauck R, et al. *Pain Pract*. 2013.	DPN	421	12	No	1200 mg/day
				No	2400 mg/day
				No	3600 mg/day
Gorson KC, et al. *J Neurol Neurosurg Psychiatry*. 1999.	DPN	40	6	No	900 mg/Day
Atkinson JH, et al. *Pain*. 2016.	Low back pain/radiculoapathy	108	12	No	Titration up to 3600 mg/day
McCleane GJ. *Pain Clin*. 2001.	Low back pain/radiculopathy	65	8	No	Titration up to 1200 mg/day
Baos S, et al. *Anesthesiology*. 2025.	Major cardiac, thoracic and abdominal surgery postoperative pain	1196	16	No	600 mg given 2 h preoperatively and 300 mg taken 2 times a day postoperatively
Punjani N, et al. *J Urol*. 2024.	Perioperative scrotal surgery pain	70	1	No	600 mg given 2 h preoperatively and 300 mg taken 3 times a day postoperatively
Lerner DK, et al. *Am J Otolaryngol*. 2024.	Perioperative endoscopic sinus surgery pain	35	1	No	Titration up to 900 mg/day
Horne AW, et al. *Lancet*. 2020.	Chronic pelvic pain	306	16	No	Titration up to 2700 mg/day
Lewis SC, et al. *PLoS One*. 2016.	Chronic pelvic pain	47	26	No	Titration up to 2700 mg/day
Smith DG, et al. *J Rehabil Res Dev*. 2005.	Phantom limb pain	24	6	No	Titration up to 3600 mg/day
Tsui JI, et al. *PLoS One*. 2024.	Chronic pain among people with HIV with alcohol use	30	8	No	Titration up to 1800 mg/day
Hahn K, et al. *J Neurol*. 2004.	HIV neuropathy	26	4	No	1200 mg to 2400 mg/day
Fowler C, et al. *Anesth Analg*. 2023.	Severe acute pain after cesarean delivery	70	12	No	Titration up to 1800 mg/day
Anghelescu DL, et al. *Pediatr Blood Cancer*. 2020	Vincristine-related neuropathic pain	49	3	No	20 mg/kg/day
Hui AC, et al. *Eur J Neurol*. 2011.	Carpal tunnel syndrome	140	8	No	Titration up to 900 mg/day
van de Vusse AC, et al. *BMC Neurol*. 2004.	Complex regional pain syndrome	58	3	No	Titration up to 1800 mg/day
Moskowitz EE, et al. *Injury*. 2018.	Acute pain management in critically ill patients with rib fractures	40	4	No	Titration up to 900 mg/day
Dworkin RH et al. *Pain*. 2009.	Acute zoster	87	4	No	Maximum dosage of 1800 mg/day

(Continued)

TABLE 1 (Continued)

Study	Condition	No. of participants	Duration (weeks)	Significant difference in pain compared to placebo	Gabapentin dose
Gordh TE, et al. *Pain*. 2008.	Traumatic nerve injury	120	5	No	Maximum dosage of 2400 mg/day
Backonja M, et al. *JAMA*. 1998.	DPN	165	8	Yes 1.1 on 0–10 scale, $p < .001$	Titrated from 900 mg to 3600 mg/day or maximum tolerated dosage
Sandercock D, et al. *Diabetes Res Clin Pract*. 2012.	DPN	147	4	Yes 1.2 on 0–10 scale, $p = .002$	3000 mg PM 1200 mg AM/1800 mg PM
Simpson DA. *Neuromuscul Dis*. 2001.	DPN	60	8	Yes 1.9 on 0–10 scale, $p < .01$	3600 mg/day
Costa GB, et al. *J Perianesth Nurs*. 2024.	Perioperative inguinal hernioplasty pain	77	4	Yes 2.0 on 0–10 scale, $p < .001$	900 mg/day
AbdelHafeez MA, et al. *Arch Gynecol Obstet*. 2019.	Chronic pelvic pain	60	24	Yes 1.8 on 0–10 scale, $p < .001$	Titration up to 2700 mg/day
AbdelHafeez MA, et al. *Arch Gynecol Obstet*. 2019.	Chronic pelvic pain	60	24	Yes 1.8 on 0–10 scale, $p < .001$	Titration up to 2700 mg/day
Bone M, et al. *Reg Anesth Pain Med*. 2002.	Phantom limb pain	19	6	Yes 1.6 on 0–10 scale, $p = .03$	Titration up to 2400 mg/day or maximum tolerated dose
Serpell MG et al. *Pain*. 2002.	Unspecified neuropathy	305	8	Yes 0.5 on 0–10 scale, $p = .048$	Titration up to 2400 mg/day
Levendoglu F, et al. *Spine (Phila Pa 1976)*. 2004.	Spinal cord injury	20	8	Yes 4.3 on 0–10 scale, $p < .001$	Titration up to 3600 mg/day
Arnold LM et al. *Arthritis Rheum*. 2007.	Fibromyalgia	150	12	Yes 0.9 on 0–10 scale, $p = .01$	1,200 mg to 2,400 mg/day

Abbreviation: DPN, diabetic peripheral neuropathy.

TABLE 2 Randomized clinical trials of pregabalin versus placebo for off-label treatment of pain.

Study	Clinical condition	No. of participants	Duration (weeks)	Difference in pain compared to placebo	Pregabalin dose
Kim JS, et al. *Pain*. 2011.	Central post-stroke neuropathic pain	219	13	No	150 mg to 600 mg/day
Simpson DM, et al. *Neurology*. 2010.	HIV neuropathy	302	14	No	150 mg to 600 mg/day
Simpson DM, et al. *Pain*. 2014.	HIV neuropathy	377	17	No	150 mg to 600 mg/day
Mir A, et al. *Breast J*. 2020	Postoperative pain in breast cancer patients	150	24	No	150 mg/day
Hincker A, et al. *Pain*. 2019	Chemotherapy-induced peripheral neuropathy	23	10	No	150 mg to 600 mg/day
Mathieson S, et al. *N Engl J Med*. 2017.	Acute and chronic sciatica	209	8	No	150 mg to 600 mg/day
Schlaeger JM, et al. *Pain Manag Nurs*. 2017.	Chronic sickle cell disease related pain	22	12	No	75 mg to 600 mg/day
Holbech JV, et al. *Pain*. 2015.	Various neuropathic pain syndromes	73	5	No	300 mg/day
Markman J, et al. *J Neurol*. 2018	Post-traumatic peripheral neuropathic pain	539	15	No	150–600 mg/day
Krcevski Skvarc N, et al. *Wien Klin Wochenschr*. 2010.	Acute zoster herpetic neuralgia	29	3	No	300 mg/day
Pontari MA, et al. *Arch Intern Med*. 2010.	Chronic prostatitis/chronic pelvic pain syndrome	324	6	No	150 mg escalated to 600 mg/day
van Seventer R, et al. *Eur J Neurol*. 2010.	Post-traumatic peripheral neuropathic pain	367	8	Yes 0.62 on 0–10 scale, $p = .01$	150 mg to 600 mg/day
Olesen SS, et al. *Gastroenterology*. 2011.	Chronic pancreatitis	64	3	Yes 0.58 on 0–10 scale, $p = .02$	150 mg escalated to 600 mg/day
Vranken JH, et al. *Pain*. 2008.	Central neuropathic pain	40	4	Yes 2.18 on 0–10 scale, $p = .01$	300 mg to 600 mg/day
Bismaya K, et al. *Clin J Pain*. 2023.	Carpal tunnel syndrome	131	6	Yes 1.63 improvement on 1–55 point scale. $p = .025$	50 mg escalated to 150 mg/day

Misuse of gabapentionoids is growing—20% of prescriptions exceed FDA-approved limits on dose; among those with substance use disorders, gabapentin and pregabalin misuse rates are reported to be 13.8% and 14.8%, respectively.[28] Poison control center reports of gabapentinoid-related exposures increased by over 230% from 2012 to 2019, with 22% resulting in serious harm, including 96 fatalities.[29] Dependence, tolerance, and withdrawal are well-documented, even at therapeutic doses.

Gabapentin and pregabalin are eliminated by the kidneys with minimal metabolism; the clearance of these drugs correlates with creatinine clearance.[30] However, in practice, dosage is not adjusted for impaired renal function in about half of hospitalized patients.[31,32] Even modest overdosing can cause marked neurotoxicity.

WHEN YOU MIGHT CONSIDER USING GABAPENTINOIDS

In this article, we address acute on chronic pain. Although we address the use of gabapentinoids with acute post-operative pain, the use of these drugs for acute neuropathic pain is much more complex and beyond the scope of this review. Regardless of the modest efficacy of these drugs found in clinical trials, some patients report a significant reduction in neuropathic pain, even for acute pain. Physicians might consider an N-of-1 trial in such a circumstance, with a clear plan on the duration of therapy, criteria for assessing effectiveness, conditions for discontinuation, and necessary safeguards and monitoring.[33] Hospitalists are well positioned to closely observe the medication's effects during the hospital stay. If the patient is to be discharged, hospitalists can further educate the patient and ensure the primary care physician is informed about continued care.

WHAT WE SHOULD DO INSTEAD

Gabapentinoids should not be assumed effective for all neuropathic pain conditions or used as routine opioid substitutes. Off-label use for pain may not provide a patient with net benefit due to oft-limited efficacy and potential harm. A thorough patient discussion is essential before prescribing. When ineffective or toxic, discontinuation is recommended. Deprescribing through gradual tapering—typically 1–2 weeks, or 4–8 weeks for long-term or high-dose users—may minimize withdrawal symptoms.

Nonpharmacological approaches targeting pain mechanisms may be a better choice. Physical therapy improves strength and mobility, while cognitive-behavioral therapy and mindfulness modify pain perception and emotional response. Evidence supports exercise, massage, and mindfulness for pain reduction, improved function, and psychological well-being, though access barriers remain. Further research is needed to develop safer pain treatments.

RECOMMENDATIONS

1. Avoid routine prescription of gabapentinoids for pain. If started in the hospital, reassess the need at discharge and discontinue unless clearly beneficial. In rare circumstances where there is an apparent net benefit to the patient, treatment should be regularly monitored and discontinued if ineffective or if significant adverse effects occur. Use renally adjusted dosing of these drugs and collaborate with a pharmacist when appropriate for medication reconciliation and patient education.
2. When a gabapentinoid has been prescribed prior to admission, hospitalists can help assess efficacy and safety and develop a deprescribing plan when appropriate. A deprescribing plan can be started in the hospital and continued by the primary care physician after discharge.
3. Consider physical therapy or other non-pharmacological modalities instead of gabapentinoids for acute on chronic pain, chronic musculoskeletal pain, or fibromyalgia.

CONCLUSION

Clinicians are advised to consider the absence of strong research results showing reliable efficacy of gabapentionoids, coupled with the high rate of adverse drug effects, when making prescribing decisions. For the patient in our scenario, a hospitalist evaluated the patient and noted poor efficacy. Gabapentin was weaned, the dose of acetaminophen was increased, and the patient was referred to physical therapy.

CONFLICT OF INTEREST STATEMENT

The authors declare no conflicts of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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